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United States Senate

WASHINGTON, DC 20510-3205

December 11, 2018

The Honorable Dr. Scott Gottlieb, M.D.
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Gottlieb,

With the passage of the Food Safety Modernization Act (FSMA) in 2010, Congress took major steps to improve food safety and protect consumers from foodborne illnesses. The law expanded the tools available to the Food and Drug Administration (FDA) to establish new preventive controls and food safety plans at food manufacturing facilities and on farms, improve the inspection of imported foods, enhance surveillance of foodborne illness outbreaks, and conduct mandatory recalls of dangerous food products. While the American food system remains the safest in the world, it has proven difficult to decrease the overall rates of foodborne illness and urgent work is needed to improve the existing food safety system. The Centers for Disease Control and Prevention (CDC) estimates that 48 million Americans get sick, 128,000 are hospitalized, and 3,000 die from foodborne disease each year.

Recalls are an important element of the FDA's response to a severe outbreak of foodborne illness. It is the final opportunity for food safety regulators to remove dangerous food products that may have already found their way onto grocery store shelves or into the refrigerators of families across the country. However, consumers can only act to protect themselves if they know that a product they purchased has been recalled. Therefore, I draw your attention to a key provision of FSMA that is vital to improving food recalls that remains unimplemented eight years after the law was enacted. Section 211 (g-h) "Grocery Store Notification" and "Consumer Notification" require grocery stores to display recall notifications where shoppers will see them; at the register, at the shelf where a recalled product was stocked, or through targeted outreach based on customer loyalty program data. These proactive actions would help make consumers aware if they had purchased an unsafe product without obligating them to actively monitor government recall notification websites or be fortunate to have learned about the recall from news reports. Many grocery stores already use these techniques, but in order to ensure customers don't ingest a recalled product stored in their pantry, they must be directly notified.

Recalls such as one this summer for a popular children's cereal could be more effective, and if parents were alerted that the unopened cereal box in their pantry should not be eaten, they could take action to keep their kids safe. The FDA has worked diligently to implement FSMA and work with key stakeholders from farm through distribution to prevent foodborne illness and improve recalls but the final step, the notification of the consumer, remains incomplete. I urge you to begin immediately the process of issuing guidelines for grocery stores so that they can notify their customers in a timely, accurate, and actionable manner. Further, I ask that you provide detailed responses to the following questions:

1. What actions has the FDA taken to date to provide grocery stores with the tools necessary to notify their customers in the event of a food recall?
2. What is the timeline for the completion of regulations required under Section 211 (g-h) "Grocery Store Notification" and "Consumer Notification"?
3. How will FDA educate grocery store operators and other food retailers about new regulations to ensure that these policies will be implemented in a manner that improve consumer awareness of recalls?
4. How will FDA monitor the compliance of grocery store operators and other food retailers with these regulations in the future?
5. How will the FDA implement and monitor compliance amongst e-commerce based grocery stores and grocery delivery companies?

I thank you for your efforts and the work of the FDA staff to improve the safety of our food system and look forward to supporting the Agency as it continues its' progress.

Sincerely,



Kirsten Gillibrand
United States Senator